

REMARKS

This application has been reviewed in light of the Office Action mailed March 15, 2010. Reconsideration of this application in view of the below remarks is respectfully requested. By this paper, claims 1-6, 9-17, 19-30, 32, 37-39 and 46 have been amended. Claims 7, 8, 18, and 41 have been cancelled. Applicant respectfully submits that no new matter has been added by these amendments.

The non-final Office Action of March 15, 2010 has been carefully considered. It is respectfully submitted that all issues raised are traversed, being hereafter addressed with reference to the relevant headings appearing in the Detailed Action section of the Office Action.

Election/Restriction

Applicant notes that claim 39 was incorrectly marked as being withdrawn in the reply to the Election/Restriction requirement. However, Claim 39 is dependent from claim 1 and is thus linked to the elected invention. Therefore, Applicant respectfully requests withdrawal of the restriction with respect to Claim 39.

Claim Rejections – 35 U.S.C. § 101

The Examiner has rejected claims 1-30, 32, 37-38 and 46 under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter.

Independent claim 1 has been amended to incorporate the limitations of claim 41 so that claim 1 now recites "*the method being performed by a processing system*". Claim 1 has also been amended to specifically recite "*using the processing system*" in the b) "*analyzing...*" and c) "*determining...*" steps of the method.

Applicant respectfully submits that the amended claim 1 requires the steps of the method to be performed on a machine, and thus the amended claim 1 is directed towards

statutory subject matter. Claims 1-6, 9-17, 19-30, 37-39 and 46 are similarly directed towards statutory subject matter by virtue of their dependence upon claim 1.

Additionally, Applicant notes that claim 32 is directed towards an apparatus comprising a processing system. Therefore, claim 32 is believed to be directed towards statutory subject matter.

Accordingly, Applicant respectfully requests withdrawal of the rejection with respect to Claims 1-30, 32, 37-38 and 46 under 35 U.S.C. § 101.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 3, 6, 8, 9, 18 and 22 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Regarding claim 3, the disclosure specifically defines what is meant by “*rapidly changing attributes*” and “*slowly changing attributes*”. (See: paragraphs [0180] - [0181]). Specifically, the disclosure defines “*rapidly changing attributes*” as changing on a day to day basis, while “*slowly changing attributes*” are defined as typically changing gradually over a number of months or years. Thus, one of ordinary skill in the art, in light of the disclosure, would be fully capable of ascertaining the requisite degree of change for both the state variables and parameter values recited in the claims. Therefore, the rejection is believed to be traversed with respect to Claim 3.

Regarding claims 6, 8, 9, 18 and 22, clarifying amendments have been incorporated to the wording of those claims. Claim 6 has been amended to incorporate the limitations of claim 8 to clarify the term “*desired behavior*”, and to clarify the meaning of the term “*acceptable*”. Claim 9 has been amended to clarify the meaning of the term “*sufficiently*”.

smooth". Claim 18 has been amended to clarify the meaning of the term "*unacceptable*". Claim 22 has been amended to clearly recite "*determining ... system values*". Similar amendments have been made to other claims where appropriate.

Although the Examiner has not rejected claim 16 as being indefinite, this claim has been amended to clarify the term "*undesired behavior*" as recited in that claim, in a similar fashion to the amendments to claim 6 mentioned above.

The Applicant submits that the claims as amended now particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Accordingly, Applicant respectfully requests withdrawal of the rejection with respect to Claims 3, 6, 8, 9, 18 and 22 under 35 U.S.C. § 112, second paragraph.

Claim Rejections – 35 U.S.C. § 103(a)

The Examiner has rejected the independent claim 1 under 35 U.S.C. § 103(a) as allegedly obvious over "Extracting Model Equations from Experimental Data" by *Friedrich et al.* in view of WO 94/06088 by *Sillen*.

Firstly, *Friedrich et al.* does not relate to "*a method of determining a treatment program for a subject*" as per claim 1. *Friedrich et al.* disclose a method for generating dynamic equations underlying observed data. Section 4 of the disclosure of *Friedrich et al.* demonstrates the ability of the disclosed method to differentiate between Parkinson's disease and other tremor conditions. However, the disclosure of *Friedrich et al.* does not disclose determining a treatment program for a subject, and does not teach towards, or suggest, treating the subject or controlling the progression of the subject's condition in any manner. The method of *Friedrich et al.* merely allows different forms of tremors to be distinguished. Accordingly, it is

respectfully submitted that the skilled person would not consider *Friedrich et al.* to be particularly relevant to the claims.

Even if the skilled person did consider the teachings of *Friedrich et al.* to be relevant, which Applicant does not concede, Applicant respectfully submit that the claims include additional distinctions over *Friedrich et al.*

For example, the graphs generated by the data as shown in Figure 4 of *Friedrich et al.* are not generated using a model of any of the conditions. Instead, those graphs represent the phase space of measured trajectories, generated from measured time series data, which represent the historical states of a condition without any indication of the progression of the condition beyond what is provided by the measured time series.

In order to clarify the distinction between the claimed trajectories and the measured trajectories of *Friedrich et al.* the claims have been amended to replace the term “trajectories” with “solution trajectories”. This terminology is used throughout the original specification, and specifically, the specification discloses, on page 10, paragraph 2, that “each solution trajectory will effectively model how the condition will potentially develop”. A skilled person would understand that the measured trajectories of *Friedrich et al.* are completely different to the solution trajectories of the claims.

Accordingly, it is respectfully submitted that *Friedrich et al.* fail to disclose the feature of claim 1 of “solution trajectories representing the progression of the condition in accordance with the model and the determined system values”.

Moreover, it is submitted that *Friedrich et al.* does not disclose “analyzing ... the subject data and model of the condition to determine system values representing the condition” as recited in the amended claim 1. Instead, the measured time series data in *Friedrich et al.* is

simply used to generate a phase space graph for the purposes of graphically describing a complex system. However, Friedrich et al. makes no mention of determining system values representing the condition by analyzing the subject data and the model.

The present Office Action concedes that *Friedrich et al.* does not disclose or suggest the claimed feature of “*determining a treatment program in accordance with the determined trajectory*”, but the present Office Action asserts that *Sillen* discloses this feature.

However, Applicant respectfully submits that there is no teaching, suggestion or motivation that would have led a skilled person to consider the teachings of *Sillen* in an attempt to improve the method of *Friedrich et al.* As discussed above, the method of *Friedrich et al.* is for generating equations underlying data measured from complex systems. Although *Friedrich et al.* mentions an application to data measured from a Parkinson's disease sufferer, this is only described as being useful in distinguishing different forms of tremor. As discussed above, *Friedrich et al.* provide no teaching or suggestion of a method having any use in treatment of a patient. Accordingly, it is submitted that if a skilled person sought to improve the disclosure of *Friedrich et al.* the skilled person would not have been motivated to consult *Sillen*, which is concerned with controlling the administration of medication.

Even if a skilled person were motivated to combine the teachings of *Friedrich et al.* and *Sillen*, which Applicant does not concede, the skilled person would not have been led to the claimed invention, as *Sillen* does not disclose using trajectories. *Sillen* merely describes controlling the administration of medication based on rules established on the basis of detected relationships between the intake of medicine and the state of health of the patient using inductive data analysis, and makes no reference on how condition progresses. Given that *Sillen* does not

disclose trajectories, it follows that *Sillen* does not teach, describe or suggest "*determining a treatment program in accordance with the determined solution trajectories*", as per claim 1.

Furthermore, a skilled person would understand that *Sillen's* rule-based approach to controlling the administration of medication, such as that detailed on page 5, lines 11-24, is incompatible with solution trajectories. Accordingly, Applicant submits that a skilled person would be unable to apply the medication control method of *Sillen* to improve a diagnostic approach using trajectories to arrive at a method having the same limitations as claim 1.

Moreover, it is respectfully submitted that *Sillen* fails to overcome the deficiencies already identified above with respect to *Friedrich et al.*

In light of the above, Applicant respectfully submits that claim 1 is novel and non-obvious over *Friedrich et al.* and *Sillen*.

The present Office Action rejects independent apparatus claim 32, which has similar limitations to claim 1, for substantially the same reasons as provided in the rejection of claim 1. Accordingly, Applicant respectfully submits that claim 32 is also novel and non-obvious over *Friedrich et al.* and *Sillen* for similar reasons as set out above.

Similarly, Applicant submits that the remaining claims are novel and non-obvious by virtue of their dependence upon claim 1.

Applicant notes that the rejections of each of the dependent claims relies on at least the disclosures of *Friedrich et al.* and *Sillen*, with a number of the rejections also being in view of one or more additional citations. A number of the dependent claims also contain further patentable distinctions over the prior art cited by the Examiner, as will be discussed below. Moreover, the additional documents cited by the Examiner fail to overcome the deficiencies of *Friedrich et al.* and *Sillen* discussed above, and this will also be discussed further below.

The Examiner has rejected dependent claims 2-5, 21-30, 37, 38 and 41 as allegedly being unpatentable over *Friedrich et al.* in view of *Sillen*. However, Applicant respectfully submits that the limitations of a number of these claims are not shown by either *Friedrich et al.* or *Sillen*.

For example, with regards to the features recited in claim 3, neither *Friedrich et al.* nor *Sillen* disclose or suggest “system values comprising state variable values representing rapidly changing attributes and parameter values representing slowly changing or constant attributes”.

Regarding the features recited in claim 4, neither *Friedrich et al.* nor *Sillen* disclose or suggest “determining control variable values, the control variables representing attributes of the condition that can be externally controlled”. Instead, *Friedrich et al.* disclose a d-dimensional stochastic vector having a deterministic part and a stochastic part, with the stochastic part including terms representing white noise. However, no mention is made that the terms representing white noise in the stochastic part are at all externally controlled. Rather, the white noise is inherent to the system itself (see the last paragraph of Section 1). In fact, *Friedrich et al.* and make no mention of external control of variables whatsoever.

Furthermore, neither *Friedrich et al.* nor *Sillen* mention stability sets or any equivalent principles, and therefore neither of these citations disclose the features of claims 23-27. It is further submitted that a skilled person would understand that *Sillen's* rule-based approach to controlling the administration of medication, such as that detailed on page 5, lines 11-24, is incompatible with stability sets, such that it would be impossible for a skilled person to modify the medication control method of *Sillen* to incorporate the use of stability sets as per claims 23-27.

Accordingly, Applicant respectfully requests withdrawal of the rejection with respect to Claims 1-5, 21-30, 32, 37, 38 and 41 under 35 U.S.C. § 103(a) over *Friedrich et al.* in view of *Sillen*.

Additionally, claims 6-11 and 15 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over *Friedrich et al.* in view of *Sillen* and further view of “Control of a Chaotic System” by *Vincent et al.*

Vincent et al. fails to overcome the deficiencies identified above with respect to *Friedrich et al.* and *Sillen*. Specifically, *Vincent et al.*, taken alone or in any proper combination with *Friedrich et al.* and *Sillen*, fails to disclose or suggest “analyzing ... the subject data and a model of the condition to determine system values representing the condition; determining ... one or more solution trajectories representing the progression of the condition in accordance with the model and the determined system values; and determining a treatment program in accordance with the determined solution trajectories” as recited in claim 1 from which claims 6-11 and 15 depend.

Further, with respect to claim 6 (which has been amended to include the limitations of claim 8) and claim 9, *Vincent et al.* does not express any opinion regarding desirability of a behavior in general, nor the specific criteria recited in claims 6 and 9. Moreover, *Vincent et al.* fails to disclose identifying acceptable trajectories based on the trajectories being “sufficiently smooth so that the solution trajectories do not adversely affect the subject”. These criteria are not disclosed or suggested in either *Friedrich et al.* or *Sillen*.

Furthermore, *Sillen* fails to disclose, teach or suggest the concepts of stable points, as per claims 6 and 16, or the concept of stability, which is directly referred to in claims 10 and 17 and which the skilled person would understand to be an element of the use of a Liapunov

function in claims 12-14. With reference to the object and advantage statements of *Sillen* on page 3, lines 7-27, it is clear that neither stable points nor the concept of stability are disclosed, explicitly or implicitly, or even suggested. Although *Vincent et al.* mentions stability, it is respectfully submitted that the skilled person would have no teaching, motivation or suggestion towards modifying the rule-based medication control method of *Sillen* to incorporate a stability analysis method as per *Vincent et al.* Accordingly, it is respectfully submitted that claim 10 and its dependent claims would not be obvious over *Vincent et al.*, *Friedrich et al.* and *Sillen* for this additional reason.

Therefore, for at least the reasons presented, claims 6, 9-11 and 15 are believed to be allowable over *Vincent et al.*, *Friedrich et al.* and *Sillen*. Accordingly, Applicant respectfully requests withdrawal of the rejection with respect to claims 6, 9-11 and 15 under 35 U.S.C. § 103(a) over *Friedrich et al.* in view of *Sillen* and further in view of *Vincent et al.*

Furthermore, claims 12-14 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over *Friedrich et al.* in view of *Sillen* in further view of “Liapunov Functions: Geometry and Stability” by *Tuljapurkaar et al.* Claims 16-18 are rejected as allegedly being unpatentable over *Friedrich et al.* in view of *Sillen* in further view of *Vincent et al.* in further view of “Treatment Strategies for the Management of Chronic Illness: Is Specialization Always Better?” by *Veazie et al.* Moreover, the Examiner has rejected claims 19-20 as being allegedly unpatentable over *Friedrich et al.* in view of *Sillen* in further view of *Vincent et al.* in further view of *Tuljapurkaar et al.* Finally, the Examiner has rejected claim 46 as being allegedly unpatentable over *Friedrich et al.* in view of *Sillen* in further view of *Veazie et al.*

With respect to *Veazie et al.* and *Tuljapurkaar et al.*, neither reference, taken alone or in any proper combination with *Friedrich et al.*, *Sillen* and/or *Vincent et al.*, overcomes the deficiencies identified above.

It should be noted the disclosure of *Tuljapurkaar et al.* relates to ecological models rather than models for the medical application of determining a treatment program for a subject, as per the claimed invention. In light of this, Applicant respectfully submits that the skilled person would not have considered the *Tuljapurkaar et al.* reference to be particularly relevant to attempts to improve the methods of *Friedrich et al.*, *Sillen* and/or *Vincent et al.*, or any combination thereof. Applicant submits that the skilled person would see no teaching, motivation or suggestion to consult the teachings of *Tuljapurkaar et al.* in this regard.

Even in the event that a skilled person were motivated to consult the teachings of *Tuljapurkaar et al.*, no mention of “*using a Liapunov function to determine the one or more control programs*” as recited in claim 12, or “*determining control variable values that result in solution trajectories travelling down the gradient of the Liapunov function in accordance with the constraints*” as recited in claim 13 is made in *Tuljapurkaar et al.*

Furthermore, the teachings of *Tuljapurkaar et al.* in fact point out limitations of Liapunov functions, concluding that considerable care must be taken in using these as a guide to stability under perturbations. Given this, a skilled person consulting the disclosure of *Tuljapurkaar et al.* would not have been obviously led to incorporate the use of Liapunov functions as an improvement to the teachings of the other cited disclosures.

It should also be noted that trajectories are not disclosed at all in *Veazie et al.* or *Tuljapurkaar et al.* Consequently, neither reference describes “*defining a second Liapunov function for which the gradient defines modified solution trajectories moving towards the*

undesired points; and determining Nature values that result in modified solution trajectories travelling down the gradient of the second Liapunov function in accordance with the constraints”, as recited in claim 19.

Moreover, none of the references disclose or suggest determining the treatment program in accordance with control programs and the Nature programs by: *“determining starting points having modified solution trajectories for which control programs exist; and determining starting points having modified solution trajectories for which Nature programs exist”, as recited in claim 20.*

Accordingly, Applicant respectfully requests withdrawal of the rejection with respect to Claims 12-14 and 16-18 under 35 U.S.C. § 103(a) over *Friedrich et al.* in view of either *Veazie et al.* or *Tuljapurkaar et al.*

CONCLUSIONS

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims presently pending in the application, namely, Claims 1-6, 9-17, 19-30, 32, 37-39 and 46 are believed to be in condition for allowance and patentably distinguishable over the art of record.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call Applicant's undersigned attorney at the number indicated below.

Respectfully submitted,

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